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EXAMINER

YANG, NELSON C

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/911,253 | <b>Applicant(s)</b><br>VIRTANEN, JORMA |  |
|                              | <b>Examiner</b><br>Nelson Yang       | <b>Art Unit</b><br>1641                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20, 34-39, 41 and 43-85 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 and 44-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-39, 41, 43 and 81-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/25/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendment of claim 34 is acknowledged and has been entered.
2. Applicant's cancellation of claims 40, 42 is acknowledged and has been entered.
3. Applicant's addition of claims 81-85 is acknowledged and has been entered.
4. Claims 34-39, 41, 43, and 81-85 are currently under examination.
5. Claims 1-33, 44-80 have been withdrawn.

### ***Rejections Withdrawn***

6. Applicant's arguments, see p. 15-16, filed November 9, 2005, with respect to the objections to the drawings and the specification have been fully considered and are persuasive. The objection to the drawings and the specification has been withdrawn.

7. Applicant's arguments, see p. 16-18, filed November 9, 2005, with respect to the rejections under 35 U.S.C. 112, have been fully considered and are persuasive. The rejection of claims 34-43 under 35 U.S.C. 112, second paragraph and first paragraph, has been withdrawn.

### ***Specification***

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: support in the specification could not be found for a first exterior surface and a second exterior surface.

### ***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 34-39, 41, 43, 81-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 34 recites a first exterior surface and a second exterior surface. It is not entirely clear what these terms are referring to, nor do the drawings appear to show these features. Further clarification is requested. Currently it the first and second exterior surfaces are interpreted to refer to first and second locations on the disk.

12. The remaining claims are rejected due to their dependence on an indefinite claim.

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 34 recites a first exterior surface and a second exterior surface. The specification, however, fails to define a first exterior surface and a second exterior surface, and it is unclear what part of the invention these terms are referring to.

***Claim Rejections - 35 USC § 102***

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15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 34-35, 38-41, 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Mian et al [US 6,319,469].

With respect to claim 34, Mian et al teach a disk comprising sample inlet ports, fluid microchannels, reagent reservoirs, reaction chambers, detection chambers, and sample outlet ports (column 3, lines 35-42). Specific sites (spatially addressable assay sites) on the disk also comprise elements that allow fluids to be analyzed, including thermal sources, light sources, as well as detectors for these effectors (column 3, lines 50-57). Excitation sources include lasers, which are focused on an optically-transparent section (first exterior surface) of the disk (column 21, lines 30-36). These optical windows are included at appropriate positions on the disk (column 22, lines 1-5). Mian et al also teach a radiation inlet and radiation outlet (fig. 16). In these embodiments, the optical component preceding the detector can include a dispersive element to permit spectral resolution. Fluorescence excitation can also be increased through multiple reflections from surfaces in the device whenever noise does not scale with path length in the same way as with signal (column 21, lines 49-57). Fluorescence is coupled back into a waveguide on the disk (column 21, lines 50-55). Mian et al further teach that the sample chamber can be a planar waveguide, wherein the analyte interacts on the face of the waveguide and light

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absorbance is the result of attenuated total internal reflection (i.e., the analyte reduces the intensity source light if the analyte is sequestered at the surface of the sample chamber, using, for example, specific binding to a compound embedded or attached to the chamber surface (column 22, lines 8-35). Mian et al also teach that light scattering detection methods may be used where light scattered by particles in a sample such as cells is collected at several angles over the illuminated portion of the channels (first and second exterior surfaces) (column 23, lines 10-23).

17. With respect to claim 35, Mian et al teach an embodiment where an immobilized antibody is presented to a sample to be tested for the antigenic analyte specific for the immobilized antibody. A second antibody, specific for a different epitope of the same antigen is subsequently bound, making a "sandwich" of the antigen between the two bound antibodies. In such assays, the second antibody is linked to a detectable moiety, such as a radiolabel or fluorescent label, or an enzymatic or catalytic functionality. For example, horseradish peroxidase or alkaline phosphatase are used to produce a color change in a substrate, the intensity of which is related to the amount of the second antibody bound in the sandwich (column 35, line 60 – column 36 – line 9).

18. With respect to claim 38, Mian et al teach that specific sites on the disk comprise elements that allow fluids to be analyzed, including thermal sources, light sources, as well as detectors for these effectors (column 3, lines 50-57).

19. With respect to claim 39, Mian et al teach a multiplicity of microsystems on a disk, with reaction chambers (column 4, lines 38-55, figs. 1A-1C), and that hybridization/denaturation analysis can be performed with a battery of precharacterized test probes, where hybridization and

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denaturation are multiplexed, using probes detectably labeled with different detectable labels so that each probe can be identified (column 45, lines 5-12).

20. With respect to claim 41, the disk contains resident software (column 35, lines 50-60).

21. With respect to claim 43, the disk appears to be coated with hydrophilic coatings such as silanes and siloxanes (column 14, lines 59-62).

22. With respect to claim 81, Mian et al teach a mirror positioned at a 45° angle to the direction of the illuminating beam (column 53, lines 20-25).

23. With respect to claim 83, Mian et al teach optical windows transparent to wavelengths used are included at appropriate positions (column 22, lines 1-6).

24. With respect to claim 84, the radiation transmissive body can comprise a cross-sectional area of a flow channel (hollow interior geometry) (column 23, lines 11-15).

25. With respect to claim 85, the channels can be arranged radially (column 40, lines 20-25).

***Claim Rejections - 35 USC § 103***

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

27. Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al [US 6,319,469] in view of Rothschild et al [US 5,986,076].

With respect to claim 36, Mian et al teach an assay system comprising a first immobilized antibody specific for an analyte and a second antibody specific for the analyte, where the second

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antibody is attached to a detectable moiety (column 35, line 61 – column 36, line 9). Mian et al do not teach that the detectable moiety is attached to a photocleavable spacer bound to the exterior surface of the waveguide.

Rothschild et al, however, do teach detectable moieties bound to the surface of an article by photoreactive moieties (column 13, lines 10-17). Rothschild et al further teach that this allows for the controlled release of the substrate into a medium (column 13, lines 8-10), and also teach that since the detectable moiety, the reactive group and the photoreactive moieties are chemically separate, the properties of each can be adjusted to meet the requirements for detection of a particular substrate (column 25, lines 30-37).

Therefore, it would have been obvious in the system of Mian et al for the detectable moieties to be bound to photocleavable moieties, as suggested by Rothschild et al, in order to allow for the controlled release of the substrate into the medium, and to keep the detectable moiety, the reactive group and the photoreactive moieties chemically separate so that the properties of each can be adjusted to meet the requirements for detection of a particular substrate.

28. With respect to claim 82, Mian et al teach an assay system comprising a first immobilized antibody specific for an analyte and a second antibody specific for the analyte, where the second antibody is attached to a detectable moiety (column 35, line 61 – column 36, line 9). Mian et al do not teach the a diffraction grating for directing radiation from the radiation source into the inlet of the waveguide.

Duveneck et al, however, teach optical diffraction gratings (column 6, lines 38-41) for coupling excitation light into the waveguide (column 6, lines 30-33), and further teach that planar waveguides with integrated coupling gratings are useful for achieving a high sensitivity, a



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sufficiently great input-coupling efficiency, as strong an evanescent field as possible, and a low attenuation of the guided wave (column 3, lines 8-20).

Therefore, it would have been obvious to one of ordinary skill in the art to have optical diffraction gratings for coupling excitation light into the waveguide in the device of Mian et al, as suggested by Duveneck et al, in order to achieve a high sensitivity, a sufficiently great input-coupling efficiency, as strong an evanescent field as possible, and a low attenuation of the guided wave.

### ***Response to Arguments***

29. Applicant's arguments filed November 9, 2005 have been fully considered but they are not persuasive, as discussed above.

### ***Conclusion***

30. No claims are allowed.

31. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1641

  
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02/17/06